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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional)	
03-044	

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David B. Bonham
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Application Number	Filed
10/631,871	7/31/2003

First Named Inventor	
Sharon Mi Lyn Tan	

Art Unit	Examiner
1615	Carlos A. Azpuru

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

I am the

☐ applicant/inventor.

☐ assignee of record of the entire interest.
See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.
(Form PTO/SB/96)

☑ attorney or agent of record.
Registration number 34,297

☐ attorney or agent acting under 37 CFR 1.34.
Registration number if acting under 37 CFR 1.34 _____

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06/12/2008
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required.
Submit multiple forms if more than one signature is required, see below*.

☑ *Total of 1 forms are submitted.

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Tradeamrk Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Serial No.: 10/631,871

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REASONS FOR REQUESTING REVIEW

Rejection of Claims 1-5 and 7-21 under 35 U.S.C. 103(a)

Claims 1-5 and 7-21 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Umemura et al. US 4,902,503 (Umemura) in view of Trogolo et al US 2003/0118664 (Trogolo) and McGlothlin et al. US 6,329,444 (McGlothlin). It is respectfully submitted that this rejection is erroneous.

All presently pending independent claims are directed to medical articles that comprise an antimicrobial region, which antimicrobial region comprises *release-modulating microparticles dispersed within a latex polymer*. The release-modulating microparticles comprising an antimicrobial agent and are adapted to release the antimicrobial agent.

Umemura discloses two types of antimicrobial latex compositions. The first type contains a homogeneous blend of a natural rubber latex or a synthetic polymer latex and protein silver. See, e.g., Abstract and Claim 1. The protein silver in the first type of composition is *dissolved* in the aqueous phase of the latexes. See the Abstract, column 2, lines 58-61 ("these objects can be achieved by blending protein silver having a high solubility in water with a natural rubber latex or a synthetic polymer latex") and Examples 1-7 (protein silver dissolved). Thus, it is clear from the disclosures referred to that the protein silver is required by Umemura to be water soluble.

The second type uses a homogeneous blend of a cationic natural rubber later or a cationic synthetic polymer latex and a water-soluble silver compound. See, e.g., Abstract, col. 4, lines 45-48 ("[w]hen a cationic natural rubber latex or a cationic synthetic polymer latex is used, a water-soluble silver compound other than protein silver may be blended therewith"). Thus, as with the protein silver, the water-soluble silver compounds are *dissolved* in the aqueous phase. See also Examples 8-10 (employing an aqueous *solution* of silver nitrate). Umemura lacks any teaching of "release-modulating *microparticles* disposed within a latex polymer," as claimed. To the contrary, it is essential that the antimicrobial compound be *dissolved* in the aqueous phase of the latex. This is a direct teaching away from the present invention. *In re Baird*, 16 F.3d 380, 29 U.S.P.Q. 2d 1550 (Fed. Cir. 1994); also see the cases cited in MPEP 2141.02 VI and the cases cited therein.

Trogolo teaches microcapsules comprising an antimicrobial agent, typically in the form of a particle or particles encapsulated within a hydrophilic polymer. See Abstract and Summary of the Invention.

Trogolo teaches a method of preparing an antimicrobial resin by incorporating an antimicrobial microcapsule into a polymer matrix. See Abstract.

Trogolo, however, does not teach latex polymers as either the encapsulating polymers or the matrix polymers. Trogolo actually teaches away from such a process at paragraph [0081], where the advantages of thermal/melt processing (specifically, injection molding of parts using a mixture of microcapsules and low-density polyethylene) are disclosed, which advantages (including enhanced amounts of antimicrobial agent at the surface of the molded parts; see also claims 46-48) may be considered unique to the process disclosed and essential to the enhanced antimicrobial functioning of the resulting articles. See, e.g., MPEP 2141.02 VI and the cases cited therein. Also see the authorities cited above with respect to Umemura.

The rejection therefore relies on the combination of two references, each of which teaches away from the present claims (and from the other). The use of insoluble antimicrobials, including release-modulating microparticles, is antithetical to the teachings of Umemura. Similarly, the use of soluble silver compounds and polymer latexes is antithetical to the teachings of Trogolo.

Thus the combination of teachings is directly contrary to what one of ordinary skill would have done with any expectation of success. See MPEP 2143.02 and the cases cited therein. At the very least, the combination would have been unwarranted by the disclosure of the references. *In re Gordon*, 733 F.2d 900, 221 U.S.P.Q 1125 (Fed. Cir. 1984), *Carl Schenk, A.G. v. Norton Corporation*, 713 F.2d 782, 218 U.S.P.Q. 698, 702 (Fed. Cir. 1983), *In re Ratti*, 270 F.2d 810, 123 U.S.P.Q. 349 (CCPA 1959), MPEP 2143.01, last paragraph. Consequently, the rejection could only have been based on undue hindsight reconstruction of the references. MPEP 2142, second paragraph, *Akzo N.V. v. U.S. International Trade Commission*, 808 F.2d 1241, 1480-81, 1 U.S.P.Q.2d, 1241, 1246 (Fed. Cir. 1986), *cert. denied,* 482 U.S. 909 (1987), *Loctite Corp. v. Ultraseal Ltd.*, 781 F.2d 861, 874, 228 U.S.P.Q. 90-99 (Fed. Cir. 1985)

McGlothlin has been relied on for its teaching of dip molding various medical devices. There is no teaching in McGlothlin pertaining to antimicrobials, either soluble or as microparticles. Thus this reference adds nothing relevant to the combination of references discussed above.

For at least the above reasons, all pending claims are patentable over Umemura, Trogolo and McGlothlin.

Withdrawal of the rejection under 35 U.S.C. 103 is respectfully requested.

Claims 6 and 22

Claim 6 was allowed in the final Office Action and this status was confirmed in the Interview Summary mailed 5/2/08.

Claim 22 was objected to the final Office Action as being dependent upon a rejected based claim. In response to the final Office Action, claim 22 was amended to incorporate that base claim. However, in the Advisory Action and the Interview Summary mailed 5/2/08, it was indicated that claim 22 would be rejected in a future action under Umemura. Claim 22 has not, to date, ever been rejected over any prior art, including Umemura.